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TRANSMITT	AL	Filing Date	December 30, 2003
FORM		First Named Inventor	Reddy, Satyanarayana G.
(tobbe used for all correspondence after	er initial filing)	Art Unit	1614
(ISPE SEE IS SI SI SE	si imagi iming)	Examiner Name	Not Yet Assigned
Tolal Number of Pages in This Submis	ssion 1	Attorney Docket Number	er 60188CON2(49947)
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Fee Attached	Licensing-re	elated Papers	Appeal Communication to Board Appeals and Interferences
Amendment/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After Final	Petition to C Provisional		Proprietary Information
Affidavits/declaration(s)	Power of Atte	omey, Revocation orrespondence Address	Status Letter
Extension of Time Request	Terminal Di	sclaimer	Other Enclosure(s) (please identify below):
Express Abandonment Request	Request	r Refund	
x Information Disclosure Statement	CD, Numbe	of CD(s)	
Certified Copy of Priority Document(s)			
Response to Missing Parts/ Incomplete Application	Form PTO/SB/0	8a/b (3 pages)	narks
Response to Missing Parts	Contificate of Ex	press Mailing (1 page); closure Statement & page:	s, in duplicate);
under 37 CFR 1.52 or 1.53	Copies of refere	ences A18, A19 and 84;	
	Return Receipt	Postcard	
SIGNAT	URE OF APPLIC	ANT, ATTORNEY, OR	AGENT
irm EDWARDS & ANG	ELL, LLP		
r ndividual name Peter 2. Jauro - 32	,360		
ignature	Lair	υ	
Date July 12, 2004			

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Dated: July 12, 2004

Signature

(Peter C. Lauro, Esq.)

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Laled: July 12, 2004

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Signature:

(Peter C. Lauro, Esq.)

Docket No.: 60188CON2(49947)

(PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reddy, Satyanarayana G.

Application No.: 10/750570 Confirmation No.: 572

Filed: December 30, 2003 Art Unit: 1614

For: Cyclic Ether Vitamin D3 Compounds,

1α(OH)3-EPI-Vitamin D3 Compounds and

Uses Thereof

Examiner: No Yet Assigned

## INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56 and 1.93 Applicant hereby invites the Examiner's attention to the references listed on the attached form PTO/SB/08, in connection with the examination of the above-identified patent application. Applicant respectfully requests that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This application is a continuation application of application serial no. 10/188,320, filed on July 1, 2002, abandoned, which is a continuation application of serial no. 09/617,881, filed on July 17, 2000, issued as U.S. Patent 6,479,538, which is a divisional application of application serial no. 09/079,942, filed on May 15, 1998, issued as U.S. Patent 6, 00,294, which in turn claims priority to provisional application serial no. 60/046,690, filed on May 16, 1997

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Pursuant to 37 C.F.R. §1.98(d), copies of the remaining references listed on the PTO/SB/08 are

not enclosed because these references were submitted to, or cited by, the Office in information disclosure statements filed in one or more of the above-identified priority applications, and those statements complied with paragraphs (a)-(c) of 37 C.F.R. §1.98

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

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Dated: July 12, 2004

Respectfully submitted,

Peter C. Lauro, Esq.

Registration No.: 32,360 EDWARDS & ANGELL, LLP

P.O. Box 55874

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Attorney for Applicant

Customer Nov. 21874

PTO/SB/08a/b (08-03)
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Sheet 1 of 3

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Complete if Known					
10/750570					
December 30, 2003					
Reddy, Satyanarayana G.					
1614					
Not Yet Assigned					
60188CON2(49947)					

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	4,021,423	05/77	Baggiolini et al.	
	A2	4,038,272	07/77	Partridge, Jr. et al.	
	А3	4,188,345	08/80	DeLuca et al.	
	A4	4,206,131	06/80	Salmond	
	A5	4,595,776	06/86	Baggiolini et al.	
	A6	4,711,881	12/87	lkekawa	
	A7	4,804,502	02/89	Baggiolini et al.	
	A8	5,145,846	06/92	Baggiolini, deceased et al.	
	A9	5,206,229	04/93	Calverley et al.	
	A10	5,206,230	04/93	Ikekawa et al.	
	A11	5,389,622	02/95	Posner et al.	
	A12	5,401,733	03/95	McLane et al.	
	A13	5,428,029	06/95	Doran et al.	
	A14	5,547,947	08/96	Dore et al.	
	A15	5,789,607	08/98	Okabe	
	A16	5,824,811	10/98	Kubodera et al.	
	A17	5,830,885	11/98	Posner	
	A18	6,100,294	08/00	S.G. Reddy	
	A19	6,479,538	11/02	S.G. Reddy	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>		
	B1	EP 808,831	11/97					
	B2	EP 808,833	11/97					
	B3	FR 2545824 A	11/84					
	B4	AU 743514	05/02	S.G. Reddy				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw tine through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.usplo.gov">www.usplo.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	xaminer Cite nitials No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
-	C1	Baggiolini, E. et al., "Stereocontrolled Total Synthesis of 1α25-Dihydroxycholecalciferol and 1α,25-Dihydroxyergocalciferol," <i>J. Org. Chem.</i> 51:3098-3108 (1986)					
	C2	Bishop, J. et al., "Profile of Ligand Specificity of the Vitamin D Binding Protein for 1α,25- Dihydroxyvitamin D <sub>3</sub> and its Analogs," <i>J. Bone &amp; Mineral Res.</i> 9(8): 1277-88 (1994)					

Examiner Signature	/Taofiq Solola/	Date Considered	11/17/2008

PTO/SB/08a/b (08-03)
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Sub	Substitute for form 1449A/B/PTO			Complete if Known		
				Application Number	10/750570	
IN.	<b>IFORMATION</b>	1 DI	SCLOSURE	Filing Date	December 30, 2003	
s	TATEMENT B	3Y /	APPLICANT	First Named Inventor	Reddy, Satyanarayana G.	
				Art Unit	1614	
	(Use as many she ets as necess ary)			Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	60188CON2(49947)	

C3	Bouillon, R. et al., "Biologic Activity of Dihydroxylated 19-Nor-(Pre) Vitamin D <sub>3</sub> ," J. Bone &	
	Mineral Res. 8(8):1009-15 (1993)	
C4	Bouillon, R. et al., "Structure-Function Relationships in the Vitamin D Endocrine System," Endocrine Reviews 16(2): 200-57 (1995)	
C5	Campbell, M. et al., "Vitamin D <sub>3</sub> Analogs and Their 24-Oxo Metabolites Equally Inhibit Clonal	
	Proliferation of a Variety of Cancer Cells but Have Differing Molecular Effects," J. Cellular Biochem. 66:413-25 (1997)	
C6	Cota, J.G. et al. "Hydrotitanation-Protonation of Vitamin D <sub>2</sub> and Its Analogues: An Efficient Method for the Preparation of 10,19-Dihydrovitamins D <sub>2</sub> Including Dihydrotachysterol <sub>2</sub> " <i>Journal of Organic Chemistry</i> 53(26):6094- (1988).	
C7	Cross, H. et al., "Vitamin D Metabolism in Human Colon Adenocarcinoma-derived Caco-2 Cells: Expression of 25-Hydroxyvitamin D <sub>3</sub> -1α-hydroxylase Activity and Regulation of Sidechain Metabolism," <i>J. Steroid Biochem. Molec. Biol.</i> 62(1):21-8 (1997)	
C8	de Vos, S. et al., "Effects of Potent Vitamin D <sub>3</sub> Analogs on Clonal Proliferation of Human Prostate Cancer Cell Lines," <i>The Prostate</i> 31(2):77-83 (1997)	
C9	Dusso, A.S. et al., "On the Mechanisms for the Selective Action of Vitamin D Analogs," Endocrinology 128(4):1687-92 (1991)	
C10	Fioravanti, L. et al., "Synthetic Analogs of Vitamin D <sub>3</sub> Have Inhibitory Effects on Breast Cancer Cell Lines," <i>Anticancer Research</i> 18:1703-8 (1998)	
C11	Fleet, J. et al., "1α,25-(OH) <sub>2</sub> -Vitamin D <sub>3</sub> Analogs with Minimal in <i>Viv</i> o Calcemic Activity Can Stimulate Significant Transepithelial Calcium Transport and mRNA Expression in <i>Vitro</i> ," <i>Archives of Biochem. &amp; Biophysics</i> 329(2):228-34 (1996)	
C12	Fleet, J.C. et al., "Effect of A-Ring Diastereomers of 1α,25-Dihydroxy Vitamin D <sub>3</sub> on Calcium Transport in Caco-2 Cells," <i>FASEB J.</i> 9(3):168 (1995)	
C13	Gardner, J. et al., "Vitamin D Analog 25-(OH)-16,23E-Diene-26,27-Hexafluoro-Vitamin D <sub>3</sub> Induces Differentiation of HL60 Cells with Minimal Effects on Cellular Calcium Homeostasis," <i>J. Cellular Biochem.</i> 63:500-12 (1996)	
C14	Jung, S. et al., "1,25(OH) <sub>2</sub> -16ENE-Vitamin D <sub>3</sub> is a Potent Antileukemic Agent with Low Potential to Cause Hypercalcemia," <i>Leukemia Research</i> 18(6):453-63 (1994)	
C15	Kim, H. et al., "1,25-Dihydroxy-Vitamin-D <sub>3</sub> Enhances Antiproliferative Effect and Transcription of TGF-β1 on Human Keratinocytes in Culture," <i>J. Cellular Physiol.</i> 151:579-87 (1992)	
C16	Lemire, J. et al., "1,25-Dihydroxy-24-OXO-16ene-Vitamin D3, a Renal Metabolite of the Vitamin D Analog 1,25-Dihydroxy-16ene-vitamin D3, Exerts Immunosuppressive Activity Equal to its Parent Without Causing Hypercalcemia in vivo," <i>Endocrinology</i> 135(6):2818-21 (1994)	-
C17	Mayer, E. et al., "23,25-Dihydroxy-24-oxovitamin D <sub>3</sub> : A Metabolite of Vitamin D <sub>3</sub> Made in the Kidney," <i>Biochemistry</i> 22)(8):1798-1805 (1983)	
C18	Muralidharan, K.R., "Studies on the A-Ring Diastereomers of 1Alfa, 25-Dihydroxyvitamin D <sub>3</sub> ," <i>J. Organic Chem.</i> 58(7):1895-1899 (1993)	
C19	Norman, A. et al., "Demonstration That 1β,25-Dihydroxyvitamin D <sub>3</sub> is an Antagonist of the Nongenomic but not Genomic Biological Responses and Biological Profile of the Three A-ring Diastereomers of 1α,25-Dihydroxyvitamin D <sub>3</sub> ," <i>J. Biol. Chem.</i> 268(27):20022-30 (1993)	
C20	Okamura, W.H. et al., "Studies on vitamin D (Calciferol) and Its Analogues 13," J. Organic Chem. 43(4):574-580 (1978)	

Examiner /Taofig Solola/	Date	11/17/2008
Signature	Considered	

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Substitute for form 1449A/B/PTO				Complete if Known		
				Application Number	10/750570	
INFO	DRMATI	ON DISC	LOSURE	Filing Date	December 30, 2003	
STA	STATEMENT BY APPLICANT			First Named Inventor	Reddy, Satyanarayana G.	
				Art Unit	1614	
(Use as many sheets as necessary)			ess ary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	60188CON2(49947)	

C2	Reddy, G.S. and Tserng, KY, "Calcitroic Acid, End Product of Renal Metabolism of 1,25- Dihydroxyvitamin D <sub>3</sub> Through C-24 Oxidation Pathway," <i>Biochemistry</i> 28:1763-9 (1989)
· C2:	Reddy, G.S. et al., "Metabolism of 1a,25-Dihydroxyvitamin D <sub>3</sub> and One of its A-Ring
	Diastereomer 1a,25-Dihydroxy-3-Epivitamin D <sub>3</sub> in Neonatal Human Keratinocytes," Vitamin D:
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C2:	Reddy, G.S. et al., "Stimulation of 24R,25-dihydroxyvitamin D <sub>3</sub> Synthesis by Metabolites of
1 1	Vitamin D <sub>3</sub> ," Am. J. Physiol. 245(4):E359-64 (1983)
C24	Reddy, G.S. et al., "Study of 1,25-Dihydroxyvitamin D <sub>3</sub> Induced Alterations in the Metabolism
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C2	Reichel, H. and Norman, A., "Systemic Effects of Vitamin D," Ann. Rev. Med. 40:71-8 (1989)
C2	Scheddin, D. et al., "Synthesis and Biological Activities of 26-Hydroxy-27-Nor-Derivatives of 1-Alfa, 25-Dihydroxyvitamin D <sub>3</sub> ," <i>Steroids</i> 61(10):598-608 (1996)
C2	Schwartz, G. et al., "1,25-Dihydroxy-16-ENE-23-YNE-Vitamin D <sub>3</sub> and Prostate Cancer Cell
	Proliferation in Vivo," Urology 46(3):365-9 (1995)
C2i	Siu-Caldera, ML et al., "The Enhanced Biological Activities Ascribed to its Parent Analog, 1α ,25(OH) <sub>2</sub> -16-ene-D <sub>3</sub> ," <i>J. Steroid Biochem. Molec. Biol.</i> 59(5/6):405-12 (1996)
C29	Veyron, P. et al., "New 20-Epi-Vitamin D3 Analogs: Immunosuppressive Effects on Skin Allograft Survival," <i>Transplantation Proceedings</i> 27(1):450 (1995)

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature	/Taofiq Solola/	Date Considered	11/17/2008

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Attorney Docket No.: 60188CON2(49947)

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Copies of references A18, A19 and B4;

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Dated: July 12, 2004

Signature:

(Peter C. Lauro, Esq.)

Docket No.: 60188CON2(49947)

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Ratent Application of: Reddy, Satyanarayana G.

Application No.: 10/750570

Confirmation No.: 5729

Filed: December 30, 2003

Art Unit: 1614

For: Cyclic Ether Vitamin D3 Compounds,

Examiner: Not Yet Assigned

1α(OH)3-EPI-Vitamin D3 Compounds and

Uses Thereof

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